UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
	Civil Action: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO ALL ACTIONS	Judge Patti B. Saris

AMGEN INC.'S CORRECTED MOTION FOR RECONSIDERATION

Amgen Inc. ("Amgen"), moves the Court to reconsider that portion of its February 24, 2004, decision denying Amgen's individual motion to dismiss the Amended Master Consolidated Complaint ("AMCC") for failure to comply with Fed.R.Civ.P. 9(b). In its decision, the Court dismissed co-defendant Hoffman-LaRoche on precisely the same grounds that were raised in Amgen's motion. Because no material basis exists for distinguishing the AMCC's allegations against Hoffman-LaRoche from those against Amgen, Amgen submits that its motion should have been granted. Additionally, that portion of a case heavily relied upon by plaintiffs in opposing Amgen's motion – *Amgen v. Scully*, 234 F.Supp 2d 9 (D.D.C. 2003) – was rejected on appeal only days prior to this Court's decision, casting serious doubt on the validity as to that aspect of plaintiffs' arguments opposing Amgen's motion.

A. There is No Discernable Difference in Plaintiffs' Allegations Against Amgen and Their Allegations Against Hoffman-LaRoche.

In its February 24 decision, the Court dismissed Hoffman-LaRoche, observing that "Defendant Hoffman-LaRoche is the *only Defendant* for which no examples of allegedly-

incriminating communications, fraudulent pricing, or government investigations were given." *In re Pharmaceutical Industry Average Wholesale Price Litigation*, Memorandum and Order (2/23/04) at 21 ("Mem. Order") (emphasis supplied). Amgen respectfully submits that this is not the case. Like Hoffman-LaRoche, plaintiffs do not allege the existence of any government investigation of Amgen, let alone any investigation relating to an alleged calculation of AWP or marketing of the so-called "spread." Similarly, like Hoffman-LaRoche, plaintiffs provide no example of "fraudulent pricing", nor do they reference any internal communication or allegedly incriminating communications by Amgen. In both cases, the only specific reference to AWP relies on publicly-available information on each of the companies' websites. *Compare* AMCC ¶ 218 *with* AMCC ¶ 419. [1/]

The only allegation that arguably distinguishes Amgen from Hoffman-LaRoche is plaintiffs' reference to a "1993 OIG Report" relating to Epogen®. This is a distinction without a difference, as the 1993 OIG study was neither an "investigation" nor even pertained to AWP. *See* OIG A-01-92-00506. To the contrary, the report was prepared in connection with the Department of Health and Human Services' consideration of possible changes to the *statutorily-fixed reimbursement rate* for Epogen® (which is *not* based on AWP), to reflect end-of-year rebates. Significantly, the report concluded that "the elimination of rebates . . would not result in a change in the manufacturer's price, nor would it serve any program end." *Id.* Simply put, the report was not part of an OIG investigation, was not based upon any allegation and did not make any finding that Amgen had done anything improper in providing rebates, and has absolutely nothing to do with the setting, marketing or manipulation of the average wholesale price for

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[1/] Indeed, if anything, these allegations as to Hoffman-LaRoche in this regard are arguably *more* detailed, in that plaintiffs allege that information on the Hoffman-LaRoche website establish that "the published AWPs for Kytril and CellCept were higher than the actual prices provided to wholesalers." *Id.* By contrast, *no* examples of how the AWPs of any Amgen product compare to actual prices are provided.

Epogen®, which was and continues to be reimbursed at a statutorily-mandated rate that is not based on AWP. *See* 42 U.S.C. § 1395rr(b)(11)(B).

Plaintiffs' allegations against Amgen are unique in one respect. Unable to point to any specific example of improper or allegedly unlawful conduct by Amgen proper, plaintiffs point to allegations against *other* defendants and assert that "[t]he logical inference is that Amgen also engaged in AWP manipulation for those drugs where the competitors were manipulating and marketing the AWP spread." AMCC ¶ 221. As the Court correctly observed in assessing the allegations against Hoffman-LaRoche, this type of "guilt-by-association" pleading does not satisfy Rule 9(b). Mem. Order at 21. In the absence of allegations concerning government investigations, internal documents or specific fraudulent spreads, singular reliance on alleged industry-wide practices is inadequate to support a claim of fraud. Mem. Order at 21. [2]/

B. That Portion of *Amgen v. Scully*, Upon Which Plaintiffs Heavily Relied in Opposing Amgen's Individual Motion to Dismiss, Has Been Rejected.

In opposing Amgen's individual motion to dismiss the AMCC, plaintiffs relied extensively on the decision of the U.S. District Court for the District of Columbia in *Amgen Inc. v. Scully,* 234 F.Supp.2d 9 (D.D.C. 2003). Citing to this case, plaintiffs claimed that the decision somehow demonstrated Amgen's acknowledgment of "over-reimbursement as a corporate-wide mechanism to gain market share" and apparently hoping to tar Amgen by reference to unrelated

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[2]/ This is particularly true in view of the First Circuit's decision in *United States ex. rel. Karvelas v. Melrose-Wakefield Hosp.*, ___ F.3d ___, 2004 WL 324465 (1st Cir. Feb. 23, 2004), issued just one day prior to the Court's decision. *Karvelas* rejected the notion that Rule 9(b)'s requirements should be relaxed in the context of a False Claims Act allegation and unequivocally reiterated the importance of Rule 9(b)'s requirement that a plaintiff asserting a fraud claim state the circumstances surrounding the alleged fraud with specificity. In that case, the First Circuit affirmed the dismissal of a false claims case in which the relator had failed to state with particularity the actual false claims submitted to the government, omitting specific reference to the identification numbers or amounts charged, the individuals involved in the alleged fraud, the dates the claims were submitted, the nature and content of documents submitted, the amounts claimed from the government, the items or services charged, and the certification of compliance with federal regulations to obtain payment. *Id.* at 9-11.

litigation involving co-defendant TAP Pharmaceuticals. *See* Plaintiffs' Opposition to Defendant-Specific Memoranda on Motions to Dismiss, at 22-24. This, too, is a distinction without a difference, as the premise for which this case is cited was rejected on appeal. As the Court of Appeals for the District of Columbia Circuit made clear, the underlying lawsuit has nothing to do with an alleged endorsement by Amgen of "over-reimbursement polices," much less a "marketing of the spread," as plaintiffs maintained. *Amgen v. Smith*, 357 F.3d 103 (D.C. Cir. 2004).

To the contrary, in concluding that Amgen had standing to challenge a decision by the Centers for Medicare and Medicaid Services ("CMS") to treat its new product, Aranesp® as functionally equivalent to Procrit®, the court put to rest any sinister purpose that plaintiffs hoped to conjure up by reference to the case:

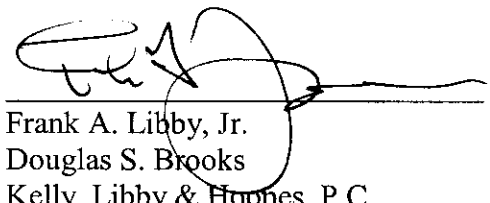
> Amgen's commercial interest in a full statutory reimbursement rate for Aranesp is neither incidental to nor antagonistic to the purpose of sec. t(6) [Medicare statutory provisions governing the Outpatient Prospective Payment System]. * * * Amgen's commercial interest in selling Aranesp is congruent with the interests of beneficiaries in obtaining access to the technology because Congress' reason for providing supplemental pass-through payments was that hospitals inadequately reimbursed for new drugs or biologicals are less likely to provide them and more likely to steer beneficiaries toward older, less expensive treatments.

Amgen Inc. v. Smith, 357 F.3d at 109.

Similarly, in finding that Amgen had standing to challenge CMS' decision, the court soundly rejected the government's (and, by extension, plaintiffs') reliance on the Fourth Circuit's decision in *TAP Pharmaceuticals v. U.S. Dep't of Health and Human Services,* characterizing the district court's reliance on that case as "misplaced." *Id.* at 10.

In conclusion, Amgen respectfully requests that its Motion for Reconsideration be granted and that the plaintiffs' claims against it be dismissed.

Respectfully submitted,



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